K101626

OCT 18 2010

4.0 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

4.1 SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON, AND DATE SUMMARY PREPARED

a. Applicant:
LenSx Lasers, Inc.
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Aliso Viejo, CA 92656
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b. Contact Person:
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c. Date Summary Prepared: June 5, 2010

4.2 NAME OF DEVICE, INCLUDING TRADE NAME AND CLASSIFICATION NAME

a. Trade/Proprietary Name: LenSx Laser System

b. Common/Usual Name: LenSx Laser System

c. Classification Name: Laser Instrument, Surgical, Powered

d. Classification Code(s): 21 CFR 886.4390; 79 OOE

4.3 PREDICATE DEVICES

510(K) #	TRADE NAME	MANUFACTURER
K082947	LenSx 550 Laser System	LenSx Lasers, Inc.
K090452	LenSx 550 Laser System	LenSx Lasers, Inc.
K092647	LenSx 550 Laser System	LenSx Lasers, Inc.
K041893	IntraLase FS Laser	IntraLase Corp. (now Abbot Medical Optics, Inc.)
K822112	Sharpoint	Angiotech
K853598	Ophthalmic Knife with Removable Depth Guide	Myocure, Inc.
K863725	Cataract Diamond Knife	Medical Technology Development Corp.

4.4 DEVICE DESCRIPTION

The LenSx Laser System uses focused femtosecond laser pulses to create incisions and separates tissue in the lens capsule, crystalline lens and cornea. Individual photodisruption locations are controlled by repeatedly repositioning the laser focus. The light pulse is focused into a sufficiently small spot in order to achieve photodisruption of the tissue inside the focus. A tiny volume of tissue, a few microns in diameter, is thereby photodisrupted at the laser focus. The surgical effect is produced by scanning thousands of individual pulses per second to produce a continuous incisions or tissue separation.

The location of the tissue photodisruption is controlled by moving the focus of the laser beam to the desired surgical target location. A computer-controlled scanning system directs the laser beam throughout a three-dimensional pattern to produce an incision. The laser pulses are delivered through a sterile, disposable applanating lens and suction ring assembly that contacts the cornea and fixes the eye with respect to the delivery system.

The LenSx Laser is an ophthalmic surgical laser that has previously been cleared for use in:

- Anterior capsulotomy (K082947), performed by delivering a cylindrical pattern of laser pulses to intersect the anterior lens capsule.
- Phacofragmentation (K090452), performed by delivering series of laser pulses to form two intersecting ellipsoidal planes that divides the lens into quadrants.
- Cuts/incisions for keratoplasty (K092647) which are performed by delivering a pattern of circles and arcs with programmable incision length and depth.

4.5 STATEMENT OF INTENDED USE

The LenSx Laser System is indicated for anterior capsulotomy and laser phacofragmentation during cataract surgery and for the creation of a partial thickness cut/incision for lamellar keratoplasty and in the creation of a full-thickness cut/incision for penetrating keratoplasty and for cataract surgery. Each of these procedures may be performed either individually or consecutively during the same surgery.

4.6 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The LenSx Laser System described in this 510(k) application is substantially equivalent to the LenSx 550 Laser System, with the same operating characteristics and principles of operation as the predicate device (K082947, K090452, and K092647). The primary differences between the LenSx Laser System and the predicate device include:

- The use of a proprietary disposable contact lens and suction device
- The addition of stepped cuts/incisions for keratoplasty and cataract surgery
- An increase in the laser repetition rate from 15 kHz to 33 kHz.
- Replacement of the LED aiming device with an interferometric aiming device
- Expanded parameter ranges for phacofragmentation diameter and depth.

4.7 BRIEF SUMMARY OF PERFORMANCE TEST RESULTS

The performance data supporting substantial equivalence of the LenSx Laser with the above modifications include:

- Comparison of the LenSx disposable contact lens/suction ring assembly (LenSx Patient Interface) with the commercially available predicate device (IntraLase Patient Interface).
- Evaluation of the accuracy and reproducibility of the depths and geometry of each of the previously cleared treatment patterns using the proprietary patient interface and modified LenSx Laser in comparison to acceptance criteria established for the predicate LenSx 550 Laser.
- Evaluation of the accuracy and reproducibility of the depths and geometry of stepped cuts/incisions using the same parameter acceptance criteria as established for single plane cuts/incisions.
- Evaluation of stepped cuts/incisions in human cadaver eyes for lamellar keratoplasty, penetrating keratoplasty and cataract surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LenSx Lasers, Incorporated
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, California 92651

Re: K101626
Trade/Device Name: LenSx Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE, HQC
Dated: October 4, 2010
Received: October 14, 2010

OCT 18 2010

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keoia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K101626

Device Name(s): LenSx Laser System

OCT 18 2010

Indications for Use:

The LenSx Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

The LenSx Laser is indicated for use in patients undergoing penetrating keratoplasty for full thickness corneal replacement and in patients undergoing lamellar keratoplasty for partial thickness corneal replacement. The intended use in penetrating and lamellar keratoplasty includes the creation of single plane and multi-plane arc and circular cuts/incisions in the cornea.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Daniel L Kaufman M.A.
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K101626